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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/826,779	04/05/2001	Nora Sarvetnick	18427-001 CON (SCRIPPS-1)	1078

7590 06/17/2002
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EXAMINER

WOITACH, JOSEPH T

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 06/17/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/826,779

Applicant(s)

SARVETNICK ET AL.

Examiner

Joseph Woitach

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL** 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-21 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other

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DETAILED ACTION

This application is a continuation of 09/212,531, filed December 16, 1998, now US Patent 6,242,666.

Applicants' amendment filed April 5, 2001, paper number 2, has been received and entered. The specification has been amended. Claims 3, 4 and 7 have been amended. Claims 18-21 have been added. Additionally, Applicants' amendment filed May 8, 2001, paper number 3, has been received and entered. The specification has been amended. Claims 1-21 are pending and currently under examination.

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1, 2 and 18, drawn to a transgenic non-human mammal whose cells comprise a polynucleotide encoding KGF operably linked to a pancreas specific promoter, classified in class 800, subclass 8.
- II. Claim 19, drawn to a transgenic non-human mammal whose cells comprise a polynucleotide encoding EGF operably linked to a pancreas specific promoter, classified in class 800, subclass 8.

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- III. Claim 3, 4 and 20, drawn to a transgenic non-human mammal whose cells comprise a polynucleotide encoding EGF and KGF operably linked to a pancreas specific promoter, classified in class 800, subclass 8.
- IV. Claims 5, 6 and 10, drawn to a method for the *in vivo* proliferation of pancreatic duct cells by providing KGF protein, classified in class 514, subclass 2.
- V. Claim 5, 6, 7, 10, 11 and 21, drawn to a method for the *in vivo* proliferation of pancreatic duct cells by providing KGF as a polynucleotide, classified in class 514, subclass 44.
- VI. Claim 8 and 9, drawn to a method for producing pancreatic duct cells in culture, classified in class 435, subclass 325.
- VII. Claims 12, drawn to a method for inhibiting beta cell development by injecting a mammal with anti α -KGF antibody, classified in class 514, subclass 2.
- VIII. Claim 13-17, drawn to a method for detecting proliferating pancreatic duct cells by detecting PDX-1 with an agent that binds PDX-1, classified in class 435, subclass 7.1.

Claims 5, 6 and 10 are generic to groups IV and V, and will be examined to the extent that they encompass the elected invention.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different

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functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to three separate transgenic animals each comprising different polynucleotides wherein the expression of the polynucleotides results in a unique phenotype for each animal.

Inventions IV-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of groups IV and V are related in that they are practice *in vivo*, however each require the administration of different agents (protein and polynucleotide). Group VI is related to groups IV and V in that pancreatic duct cells are made to proliferate, however group VI is practiced *in vitro*. Each of the methods require different materials and use different methods steps for the practice of the method. The differences between the inventions are further underscored by their divergent classification and independent search status.

Inventions IV-VI and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of groups IV-VI are directed to the proliferation of a particular cell type and group VII is directed to decreasing cell proliferation. Further, each of the methods require different materials and use different methods steps for the practice of the method. The

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differences between the inventions are further underscored by their divergent classification and independent search status.

Inventions IV-VII and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of groups IV-VIII are directed to methods for culturing cells and group VIII is directed to a method detecting the presence of a protein, PDX-1, in a sample. Each of the methods require different materials and use different methods steps for the practice of the method. The differences between the inventions are further underscored by their divergent classification and independent search status.

Inventions I-III and IV-VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different methods of groups IV-VIII do not require a transgenic animal, nor do the methods result in one. The differences between the inventions are further underscored by their divergent classification and independent search status.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

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Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (703)305-3732.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (703)305-4051.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist Pauline Farrier whose telephone number is (703)305-3550.

Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center numbers are (703)308-4242 and (703)305-3014.

Joseph T. Woitach

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AU1632